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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,605	01/23/2002	Robert Schlegel	MRI-024	9511

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LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
SAKELARIS, SALLY A	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HC

Office Action Summary	Application No.	Applicant(s)	
	10/056,605	SCHLEGEL ET AL.	
	Examiner	Art Unit	
	Sally A. Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 7 and 8, drawn to a method of assessing whether a patient is afflicted with colon cancer through protein detection, classified in class 435, subclass 7.1.

II. Claim 9, drawn to a method of assessing whether a patient is afflicted with colon cancer through antibody detection, classified in class 435, subclass 7.1.

III. Claims 10-14, drawn to a method of assessing whether a patient is afflicted with colon cancer through detection of nucleic acids as classified in for example, class 435, subclasses 6 and 91.2.

IV. Claims 21-26, drawn to a method for monitoring the progression of colon cancer in a patient as classified in for example class 435, subclass 6, or 7.1.

V. Claims 27-31 and 39, drawn to a method of assessing the efficacy of at test compound and for inhibiting colon cancer as classified in for example Class 514 subclass 44 or 12.

VI. Claims 32 and 41 are drawn to a method of inhibiting colon cancer selecting a composition for inhibiting colon cancer as classified in for example Class 514 subclass 44 or 12.

VII. Claim 34 is drawn to a kit comprising a nucleic acid probe which specifically binds with polynucleotides of the marker gene as classified in Class 536 subclass 24.1.

VIII. Claims 37 and 38 are drawn to an antibody and a kit containing the same as classified as Class 514 subclass 2.

IX. Claim 42 is drawn to a method of treating through oligo administration as classified in Class 514 subclass 44.

X. Claims 43-47 are drawn to a method of determining whether colon cancer has metastasized as classified in for example Class 435 subclass 6 or 7.1.

XI. Claims 48-52 are drawn to a method for assessing the aggressiveness or indolence of colon cancer as classified in for example Class 435 subclasses 6 or 7.1.

1. Applicant is advised that examination will be restricted to only the elected colon cancer marker gene(s) of table 1 and gene names and should not be construed as a species election.

Claims 1-6, and 15-20 link the inventions of Groups I-III.

Claims 33, 35, and 40 link Groups VII and VIII.

The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-6, 15-20, 33, 35, and 40. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

a. Inventions II and VIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of invention VIII can be used in a materially different process such as for protein purification.

b. Inventions III and VII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleotide probes in the kit of invention VII can be used in a materially different process such as for, in situ hybridization.

c. Inventions of II and VII and III and VIII and I-VI, IX-XI with both VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions using nucleic acids and antibodies respectively are unrelated as the nucleic acids cannot be used in the method requiring an antibody and vice versa.

d. Inventions VII and VIII are patentably distinct in structure and physiochemical properties. Invention VII is drawn to nucleic acids whereas invention VIII is drawn to antibodies. Because nucleic acids are composed of nucleotides and antibodies are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the antibodies may be utilized in assays to detect the presence or absence of a protein.

e. Lastly, the claimed methods of Groups I-VI and IX-XI have different objectives, require different process steps and require the use of different reagents. The method of Group I requires the steps of assessing whether a patient is afflicted with colon cancer through protein detection. The method of Group II requires the steps involved in assessing whether a patient is afflicted with colon cancer through antibody detection. Group III requires steps for assessing whether a patient is afflicted with colon cancer through detection of nucleic acids comparing polypeptide expression. Group IV involves monitoring the progression of colon cancer in a patient. Group V involves the steps of assessing the efficacy of at test compound and for inhibiting colon cancer. Group VI includes inhibiting colon cancer selecting a composition for inhibiting colon cancer. Group IX requires treating through oligo administration. Group X includes steps for determining whether colon cancer has metastasized. Finally Group XI involves steps for assessing the aggressiveness or indolence of colon cancer. In addition to the differences in objectives, effects, and method steps it is again noted that the claims are not patentably distinct since throughout different biomolecules with different structure and functions must be accommodated in each method.

Sequence Election Requirement Applicable to All Groups:

2. Portions of MPEP 803.04 are repeated herein for Applicant's convenience.

> "Examples of typical nucleotide sequence claims impacted by the partial waiver of 37 CFR 1.141 et seq. (and the partial waiver of 37 CFR 1.475 and 1.499 et seq., see MPEP § 1850) include...C) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000...Applications containing only composition claims reciting different combinations of individual nucleotide sequences, such as set forth in example (C), will be subject to a restriction requirement. Applicants will be required to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example (B). More specifically, the combination will be searched until one nucleotide sequence is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed."

Groups I-XI include claims that recite groupings of different colon cancer marker genes from Table 1. Thus, the claims read on a multitude of groupings of markers, each of which is separate and distinct one from another because they contain nucleic acid sequences, polypeptide sequences and antibody conformations that are structurally separate from one another. The search and examination of all possible groups would pose an enormous burden on the examiner and on the PTO search resources. In accordance with MPEP 803.04, applicant is required to select one combination of marker genes for examination with the elected group from those markers set forth in Table 1. Applicant must clearly define their election with respect to the corresponding SEQ ID NOS that they are electing in addition to their election of a group.

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences with different compositions are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent

evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

3. Applicant is advised that examination will be restricted to only the methods or products as they recite the elected polymorphic markers and should not be construed as a species election.

4. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance

with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris

3/9/2005

JEANINE A. GOLDBERG
PRIMARY EXAMINER